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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,291	03/02/2004	James H. Coombs	NAGACO.074A	3167
7590 Donald Bollella DB Technical Consulting 126 Almador Irvine, CA 92614			EXAMINER LUM, LEON YUN BON	
			ART UNIT 1641	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
31 DAYS			01/17/2007	
			DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/792,291	<b>Applicant(s)</b> COOMBS ET AL.	
	<b>Examiner</b> Leon Y. Lum	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, 13-14, 39-50, and 51-54, drawn to a method of detecting and quantifying a cell type, classified in class 435, subclass 7.1.
  - II. Claims 9-12, drawn to a method of making an optical bio-disc, classified in class 436, subclass 518.
  - III. Claims 15-21, drawn to an optical bio-disc, classified in class 422, subclass 50.
  - IV. Claims 22-25, drawn to a method of using the optical bio-disc, classified in class 435, subclass 287.9.
  - V. Claims 26-38, drawn to a method of identifying and quantifying various cell types, classified in class 435, subclass 288.7.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different

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functions, and different effects. Invention I is a method of using an optical bio-disc to detect and quantify a cell type, which requires the steps of applying target cells, operating the bio-disc, and performing optical detection methods, all of which are absent from the claims of Invention II. Conversely, Invention II is a method of making an optical bio-disc, which requires the steps of fabricating the bio-disc by providing encoded information and applying different biological layers, all of which are absent from the claims of Invention I.

The divergent steps between Inventions I and II constitute a difference in the modes of operation and function, since different steps are required between the methods. In addition, the effect of Invention I is to detect an analyte, which is patentably distinct from the effect of Invention II, which is to produce a physical device. Inventions I and II are therefore unrelated inventions.

3. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. The claimed bio-disc of Invention III can perform the patentably distinct process of providing antibodies for a homogenous immunoassay. The active layer on the bio-disc can conceivably be a compound comprising a cleavable substrate to an enzyme. The immunoassay comprises the steps of placing the bio-disc

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in a sample solution, wherein the plurality of capture antibodies comprise different antibody types and are attached to the bio-disc by different substrate types. Desired antibodies are released to bind to specific target analytes in the solution by supplying the solution with an enzyme specific for the substrate attached to the desired antibodies. By binding target analyte in solution, the analyte can be optically located and sorted into a separate receiving chamber for further analysis.

4. Inventions I and IV are directed to related to a method of identifying and quantifying a cell type of interest. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not capable of use together. Invention I requires a reporter agent applied to the bio-disc after sample with target cells are applied to the bio-disc surface. However, Invention IV requires a tagging agent applied to an antibody specific for target cells before the cells are applied to the bio-disc. Therefore, since the reporter agent and tagging agent perform the same function as labeling indicators and are required to be applied at different times between the two inventions, the inventions are not capable of use together. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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5. Inventions I and V are directed to related methods of identifying and quantifying various cell types of interest. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not capable of use together. Invention I requires the step of detecting tagged first cell types and untagged second cell types. However, Invention V requires the step of detecting both tagged first and second cell types. Therefore, since one invention requires second cell types of be tagged while the other invention requires them to be untagged, the inventions are not capable of use together. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. The claimed bio-disc of Invention III can perform the patentably distinct process of providing antibodies for a homogenous immunoassay. The active layer on the bio-disc can conceivably be a compound comprising a cleavable

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substrate to an enzyme. The immunoassay comprises the steps of placing the bio-disc in a sample solution, wherein the plurality of capture antibodies comprise different antibody types and are attached to the bio-disc by different substrate types. Desired antibodies are released to bind to specific target analytes in the solution by supplying the solution with an enzyme specific for the substrate attached to the desired antibodies. By binding target analyte in solution, the analyte can be optically located and sorted into a separate receiving chamber for further analysis.

7. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Invention II is a method of making an optical bio-disc, which requires the steps of fabricating the bio-disc by providing encoded information and applying different biological layers, all of which are absent from the claims of Invention IV. Conversely, Invention IV is a method of using an optical bio-disc to detect and quantify a cell type, which requires the steps of applying target cells, operating the bio-disc, and performing optical detection methods, all of which are absent from the claims of Invention II.

The divergent steps between Inventions II and IV constitute a difference in the modes of operation and function, since different steps are required between the methods. In addition, the effect of Invention IV is to detect an analyte, which is

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patentably distinct from the effect of Invention II, which is to produce a physical device.

Inventions II and IV are therefore unrelated inventions.

This relationship also applies between Inventions II and V.

8. Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. The claimed bio-disc of Invention III can perform the patentably distinct process of providing antibodies for a homogenous immunoassay. The active layer on the bio-disc can conceivably be a compound comprising a cleavable substrate to an enzyme. The immunoassay comprises the steps of placing the bio-disc in a sample solution, wherein the plurality of capture antibodies comprise different antibody types and are attached to the bio-disc by different substrate types. Desired antibodies are released to bind to specific target analytes in the solution by supplying the solution with an enzyme specific for the substrate attached to the desired antibodies. By binding target analyte in solution, the analyte can be optically located and sorted into a separate receiving chamber for further analysis.

This relationship also applies between Inventions III and V.



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9. Inventions IV and V are directed to related to a method of identifying and quantifying a cell type of interest. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not capable of use together. Invention IV requires a tagging agent applied to an antibody specific for target cells before the cells are applied to the bio-disc. However, Invention V requires a reporter agent applied to the bio-disc after sample with target cells are applied to the bio-disc surface. Therefore, since the reporter agent and tagging agent perform the same function as labeling indicators and are required to be applied at different times between the two inventions, the inventions are not capable of use together. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

10. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

In addition, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02),

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restriction for examination purposes as indicated is proper. For example, between the apparatus claims of Invention III and the method claims of Inventions I, IV, and V, the disclosure of the bio-disc apparatus in a reference does not necessarily include disclosure of methods to use the apparatus in an assay. It follows that the reference would not necessarily include a method of fabricating the bio-disc either, as required in Invention II. Furthermore, between the different method inventions, the fact that Inventions I, II, IV, and V are all incapable of operating together indicates that a reference teaching the method of one of the inventions would not teach the methods of the other inventions.

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon Y. Lum  
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Art Unit 1641



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